

DOCKET NO. 208858US0PCT



DW 3761
AP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: David LEWIS et al

SERIAL NO.: 09/831,888

GAU: 3761

FILED: July 19, 2001

EXAMINER: MITCHELL, T.K.

FOR: PRESSURISED METERED DOSE INHALERS (MDI)

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicants wish to disclose the following information.

REFERENCES

- The Applicants wish to make of record the references listed on the attached Form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

RELATED CASES

- Attached is a list of applicant's pending application(s), published application(s) or issued patent(s) which may be related to the present application. In accordance with the waiver of 37 CFR §1.98 dated September 21, 2004, copies of the cited pending applications are not provided. Cited published and/or issued patents, if any, are listed on the attached Form PTO-1449.
- A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

CERTIFICATION

- Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

DEPOSIT ACCOUNT

- Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

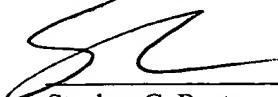
01/07/2005 GWORDDOF1 00000028 09831888

01 FC:1806

180.00 OP

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



Stephen G. Baxter
Registration No. 32,884

Customer Number

22850

Tel. (703) 413-3000
Fax. (703) 413-2220
(OSMMN 05/03)

JAN 6 2005

SHEET 1 OF 4

Form PTO 1449 (Modified)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DOCKET NO. 208858US0PCT	SERIAL NO. 09/831,888		
LIST OF REFERENCES CITED BY APPLICANT		APPLICANT David LEWIS et al					
		FILING DATE July 19, 2001		GROUP 3761			
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA	2003/0190287 A1	10/09/03	David LEWIS et al			
	AB	2003/0206870 A1	11/06/03	David LEWIS et al			
	AC	6,045,778	04/04/00	Paul Donald JAGER et al			
	AD	5,676,930	10/14/97	Paul D. JAGER			
	AE	6,413,496	07/02/02	Michael GOODMAN et al			
	AF	5,642,728	07/01/97	Jan ANDERSSON et al			
	AG	5,415,853	05/16/95	Helmut HETTCHE et al			
	AH	5,605,674	02/25/97	Tarlochan S. PUREWAL et al			
	AI	6,004,537	12/21/99	Frank E. BLONDINO et al			
	AJ	6,241,969	06/05/01	Zahir SAIDI et al			
	AK	5,891,419	04/06/99	Anthony J. CUTIE			
	AL	5,192,528	03/09/93	R. RADHAKRISHNAN et al			
	AM	4,185,100	01/22/80	David T. ROVEE et al			
	AN	6,253,762	07/03/01	Ignatius Loy BRITTO			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION		
					YES	NO	
	AO	WO 98/34595	08/13/98	WIPO			XXX
	AP	0 372 777	06/13/90	EPO			
	AQ	0 911 048	04/28/99	EPO			
	AR	WO 99/12596	03/18/99	WIPO			
	AS	WO 92/20391	11/26/92	WIPO			
	AT	WO 98/03533	01/29/98	WIPO			
	AU	1 525 181	09/20/78	GB			
	AV	WO 96/19969	07/04/96	WIPO			XXX
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	AW	S.S. DAVIS, "Physico-Chemical Studies on Aerosol Solutions For Drug Delivery I. Water-Propylene Glycol Systems", <u>International Journal of Pharmaceutics</u> , 1, 1978, pp. 71-83.					
	AX	L. Harrison et al, "Twenty-eight-day Double-blind Safety Study of an HFA-134a Inhalation Aerosol System in Healthy Subjects", <u>J. Pharm. Pharmacol.</u> , 1996, Vol. 48, pp. 596-600.					
	AY	P. Hoet et al, "Epidemic of liver disease caused by hydrochlorofluorocarbons used as ozone-sparing substitutes of chlorofluorocarbons", <u>The Lancet</u> , 1997, Vol. 350, pp. 556-559.					
	AZ	J. Daly, Jr., "Properties and toxicology of CFC alternatives", <u>Aerosol Age</u> , February 1990, pp. 26-27, 40, 56 and 57.			<input type="checkbox"/> Additional References sheet(s) attached		
Examiner					Date Considered		
*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

O I P E
JAN 06 2005
P A T E N T
T R A D E M A R K
O F F I C E
S E C T I O N
5 C 177

SHEET 2 OF 4

Form PTO 1449 (Modified)		DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DOCKET NO. 208858US0PCT	SERIAL NO. 09/831,888		
LIST OF REFERENCES CITED BY APPLICANT		APPLICANT David LEWIS et al					
		FILING DATE July 19, 2001		GROUP 3761			
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA	4,499,108	02/12/85	Joel A. SEQUEIRA et al			
	AB	5,955,058	09/21/99	Paul Donald JAGER et al			
	AC	6,150,418	11/21/00	Dieter HOCHRAINER et al			
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						
	AL						
	AM						
	AN						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION		
	AO	WO 94/14490	07/07/94	WIPO	YES	NO	XXX
	AP	WO 99/64014	12/16/99	WIPO			
	AQ	WO 00/30608	06/02/00	WIPO			
	AR	WO 00/53157	09/14/00	WIPO			
	AS	WO 97/47286	12/18/97	WIPO			
	AT	2 326 334	12/23/98	GB			
	AU	0 653 204	05/17/95	EPO			
	AV	WO 01/47493	07/05/01	WIPO			
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	AW	D. Strobach, "Alternatives to CFCs" Part II, <u>Aerosol Age</u> , July 1988, pp. 32-33, 42 and 43					
	AX	Tsai-Zong Tzou et al, "Drug Form Selection in Albuterol-Containing Metered-Dose Inhaler Formulations and Its Impact on Chemical and Physical Stability", <u>Journal of Pharmaceutical Sciences</u> , 1997, Vol. 86, No. 12, pp. 1352-1357.					
	AY	M.J. Kontny et al, "Issues Surrounding MDI Formulation Development with Non-CFC Propellants", <u>Journal of Aerosol Medicine</u> , 1991, Vol. 4, No. 3, pp. 181-187.					
	AZ	I. P. Tansey, "Changing to CFC-Free Inhalers: The Technical and Clinical Challenges", <u>The Pharmaceutical Journal</u> , 1997, Vol. 259, pp. 896-898.			<input type="checkbox"/> Additional References sheet(s) attached		
Examiner					Date Considered		
*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							



Form PTO 1449 (Modified)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DOCKET NO. 208858US0PCT	SERIAL NO. 09/831,888		
LIST OF REFERENCES CITED BY APPLICANT		APPLICANT David LEWIS et al					
		FILING DATE July 19, 2001		GROUP 3761			
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						
	AL						
	AM						
	AN						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION		
					YES	NO	
	AO	WO 91/11173	08/08/91	WIPO			
	AP	WO 93/11747	06/24/93	WIPO			
	AQ	WO 94/21228	09/29/94	WIPO			
	AR	WO 96/18384	06/20/96	WIPO			
	AS	WO 96/19198	06/27/96	WIPO			
	AT	WO 96/19968	07/04/96	WIPO			
	AU	WO 98/05302	02/12/98	WIPO			
	AV	WO 00/07567	02/17/00	WIPO			XXX
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	AW	D. Tiwari et al, "Compatibility Evaluation of Metered-Dose Inhaler Valve Elastomers with Tetrafluoroethane (P134a), a Non-CFC Propellant, <u>Drug Development and Industrial Pharmacy</u> , 1998, Vol. 24, No. 4, pp. 345-352.					
	AX	<u>Handbook of Pharmaceutical Excipients</u> , 3rd Ed., Kibbe Editor, pp. 7-9, 220-222, 234-235 and 560-561.					
	AY	L. I. Harrison et al, "Pharmacokinetics and Dose Proportionality of Beclomethasone From Three Strengths of A CFC-Free Beclomethasone Dipropionate Metered-Dose Inhaler", <u>Biopharmaceutics & Drug Disposition</u> , 1997, Vol. 18, No. 7, pp. 635-643.					
	AZ	Chet Leach, "Enhanced Drug Delivery Through Reformulating MDIs with HFA Propellants-Drug Deposition and Its Effect on Preclinical and Clinical Programs", <u>Respiratory Drug Delivery V</u> , 1996, pp. 133-144.				<input type="checkbox"/> Additional References sheet(s) attached	
Examiner					Date Considered		
*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO 1449
(Modified)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

JAN 06 2005

ATTY DOCKET NO.
208858USUS0PCTSERIAL NO.
09/831,888

LIST OF REFERENCES CITED BY APPLICANT

APPLICANT
David LEWIS et alFILING DATE
July 19, 2001GROUP
3761

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						
	AL						
	AM						
	AN						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AO	WO 98/34596	08/13/98	WIPO		
	AP	WO 00/06121	02/10/00	WIPO		XXX
	AQ	WO 99/65464	12/23/99	WIPO		
	AR	WO 00/23065	04/27/00	WIPO		XXX
	AS					
	AT					
	AU					
	AV					

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)

	AW		
	AX		
	AY		
	AZ	<input type="checkbox"/> Additional References sheet(s) attached	
Examiner		Date Considered	

*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.